DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 14, 2015

Full Power AED
Mr. Jahn Power, President
707 East Hudson Ave.
Durham, NC 27704

Re: K150349
Trade/Device Name: Rapid Hair Removal Pads
Regulation Number: 21 CFR 870.5300
Regulation Name: DC-Defibrillator (Including Paddles)
Regulatory Class: Class II (two)
Product Code: LDD
Dated: June 1, 2015
Received: June 5, 2015

Dear Mr. Jahn Power,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

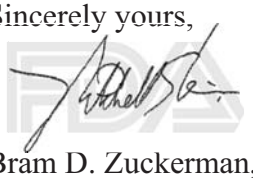
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150349

Device Name

Rapid Hair Removal Pads

Indications for Use *(Describe)*

To remove excessive hair prior to placement of defibrillator electrodes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FULL POWER
— AED —

510(k) Summary

Summary of Information Contained in the 510(k) Premarket Notification

Date: February 2, 2015

Submitter: Full Power AED, LLC
707 East Hudson Avenue
Durham, NC 27704

Contact Person: Jahn Power
President
919-475-6088

Trade name: Rapid Hair Removal Pads or "RHRP"

Common name: Chest Hair Removal Pads

Classification: The Rapid Hair Removal Pads are disposable accessories to the DC-Defibrillator, Low Energy, Product Code LDD, Class II, CFR Section 870.5300.

The Rapid Hair Removal Pads are substantially equivalent to the 700-F Series Disposable Cardiac Stimulation Monitoring Electrodes, 510(k) # K964469, manufactured by Cardiotronics.

Device Description

The Rapid Hair Removal Pads ("RHRP") are intended to be used by medical professionals prior to the placement of DC-Defibrillator, Low Energy electrodes to remove excessive chest and side torso hair from a victim of sudden cardiac arrest. This hair can significantly impede the defibrillator's performance in analyzing the heart's rhythm and delivering an appropriate shock. The primary mechanism of the RHRP is a high-tack adhesive that removes hair from the sites on the chest and side torso on which these electrodes are to be placed, prepping the site for optimal electrode-to-skin contact. RHRP is a single-use product and can be disposed of with other emergency single-use equipment.

To use the RHRP, the user removes the pads from the outer packaging, peels the pads sequentially off the non-stick PET liner backing, and places the adhesive side of the pad at two sites—on the chest and side torso—where the defibrillator electrodes will be placed. The user presses the pads on firmly to adhere them to the hair and skin at those sites. The user then pulls the pads quickly away from the skin in the opposite direction of hair growth. The resulting area is left substantially cleared of hair, decreasing impedance and increasing electrode-to-skin contact.

Intended Use

To remove excessive hair prior to placement of defibrillator electrodes.

Substantial Equivalence Determination

The RHRP is equivalent to the 700-F Series Disposable Cardiac Stimulation Monitoring Electrodes ("DCSME") in its intended use, conditions of use and anatomical sites of use. Substantial equivalence has been determined on the basis of comparisons to the DCSME's intended use, user and target populations, anatomical sites of use, limited contact duration, use environment, post-use disposal, and design. The RHRP and the DCSME are different in their mechanism of use and in their sequence of use in defibrillation therapy, but these differences are minor and do not adversely affect safety and effectiveness of the RHRP.

Substantial equivalence has also been determined by the following performance testing:

1. Human Factors/Usability testing, in which 15 Advanced Life Safety trained professionals (ALS personnel) were trained on how to use the RHRP, put into a simulated emergency setting, and timed as they used a set of the RHRP pads on a live human subject. This testing demonstrated that:
   a) Training of ALS personnel and the RHRP labeling effectively directed the users how to properly apply and remove the RHRP pads from a live subject and proposed labeling changes will further enhance the user interface;
   b) In a timed simulation, these ALS personnel were able to properly place and remove the RHRP in under 15 seconds; and
   c) No user confusion or user error was identified based on the simulation and the questionnaire responses of the ALS personnel taken after the testing.

2. Impedance testing, in which the RHRP pads were used in 26 total chest pulls; impedance readings of the site were taken with a CheckTrode Ohm meter before and after RHRP application. This testing demonstrated that:
   a) The hair removal accomplished by the RHRP adhesive substantially decreases impedance, thereby optimizing the electrode pad-to-skin contact and aiding defibrillation therapy.

3. Biocompatibility studies:
   a) Cytotoxicity test results show no detectable interaction between the RHRP and human cells, and a reactivity grade of "0;"
   (b) Human Use Testing showed that the RHRP caused only minor and temporary mechanical irritation of the skin; no chemical irritation of the skin was experienced after application and removal of the RHRP; and

(c) Analysis of the RHRP adhesive material that comes into contact with the skin (based on manufacturer records) shows that they are not toxic, do not contain color additives, and have no adverse environmental effects.

The comparisons of the RHRP to the DCSME and the results of the above testing demonstrate that: (1) the RHRP is as safe, as effective, and performs as well as the DCSME for the intended use; and (2) that the RHRP is substantially equivalent to the DCSME and is suitable for the specified intended uses in the environment for use indicated.